Drug Use Research & Management Program
Oregon State University, 500 Summer Street NE, E35
Salem, Oregon 97301-1079
Phone 503-947-5220 | **Fax** 503-947-2596

Policy Proposal: Substance Use Disorder

Purpose:
The purpose of this policy proposal is to update current prior authorization (PA) criteria to comply with new legislation.

Background:
During the 2019 legislative session, the Oregon legislature passed House Bill 2257 which declared the legislative intent to consider substance use disorder as a chronic illness.[1] The new legislation requires the Oregon Health Authority to prohibit use of prior authorization (PA) during the first 30 days of medication-assisted treatment for both opioid- and alcohol-related substance use disorders.[1] This update recommends changes to PA and preferred drug list (PDL) status to comply with this new legislation and proposes a retrospective drug use review (DUR) program with the goals of avoiding interruptions in therapy and ensuring appropriate use of long-term second-line treatment options for opioid use disorder (OUD).

Currently in fee-for-service Medicaid, treatments for OUD or alcohol use disorder available without PA include acamprosate tablets, naltrexone tablets, naltrexone extended release injection, and preferred buprenorphine/naloxone sublingual tablets and film (unless the daily dose of buprenorphine exceeds 24 mg to prevent off-label use for treatment of pain). Drug therapy for OUD or alcohol use disorder which are currently non-preferred and require PA include Bunavail® (buprenorphine/naloxone film), buprenorphine sublingual tablets, buprenorphine extended-release injection, buprenorphine implants, disulfram and lofexidine. Methadone for the treatment of OUD is required to be dispensed by a practitioner rather than dispensed through a pharmacy and is not subject to PA. The intent of the current PA criteria is to limit off-label use for pain, encourage use of monotherapy products for appropriate patients, and prevent concomitant opioid prescribing. In a previous policy evaluation of therapies for OUD, about 14% of patients prescribed OUD treatment had no diagnosis of opioid use, dependence or abuse based on claims history.

Recent high quality guidelines from the Veterans Affairs/Department of Defense (VA/DOD) recommend use of buprenorphine-naloxone or methadone as first-line treatment options for OUD (strong recommendation based on high quality evidence).[2] Similar recommendations were made in a high quality guideline from the Canadian Research Initiative in Substance Misuse published in 2018 recommending buprenorphine/naloxone as first-line therapy and methadone as a second-line option.[3] Buprenorphine monotherapy is recommended only in patients who are pregnant.[2] Current evidence indicates that, while oral buprenorphine monotherapy has similar efficacy to combination buprenorphine/naloxone, it is associated with a significantly higher rate of abuse, misuse, and diversion compared to combination buprenorphine-naloxone products.[4] Extended-release injectable naloxone may be considered as a treatment option for patients for whom buprenorphine/naloxone or methadone is contraindicated, unacceptable, or unavailable, and who have established opioid abstinence for at least 7 to 10 days based on moderate quality evidence.[2]

For treatment of alcohol use disorder, 2015 guidelines from the VA/DOD recommend choice of treatment with either acamprosate, disulfiram, naltrexone (oral or extended-release injection) or topiramate be based on individual risks/benefit assessment, specific needs, and patient preferences (strong recommendation).[2] There is insufficient evidence to recommend one agent over another, and in all cases, psychosocial interventions are recommended to successfully improve outcomes, decrease alcohol use, and improve abstinence in patients with alcohol use disorder (strong recommendation based on moderate quality evidence).[2]

Examples of psychosocial interventions may include behavioral couples counseling, cognitive behavioral therapy, 12-step programs, or motivational enhancement therapy.

In an evaluation of paid and denied claims for substance use disorder from 1/1/2019 to 3/31/2019, there were 632 patients prescribed therapies for OUD or alcohol use disorder. Patients may be counted more than once if they were prescribed multiple types of therapy. About 77% of prescribed therapy was for preferred products and 23% was for non-preferred products. All but one request for preferred therapy was initially paid or paid within 30 days of the request, indicating very little utilization of high dose buprenorphine (>24 mg/day) for preferred products. Doses exceeded 24mg per day in about 4% of members with denied claims for non-preferred buprenorphine monotherapy (n=7). The most commonly requested non-preferred product was oral buprenorphine monotherapy. Forty-four percent of patients requesting buprenorphine monotherapy (n=56) had a subsequent PA approved and 11% of patients (n=14) switched to a preferred agent. In 45% of patients with an initial denied claim, there were no paid claims for subsequent therapy. Of the patients with no subsequent paid fee-for-service claims for OUD, 92% were subsequently enrolled in a coordinated care organization, lost Medicaid eligibility, or had other insurance which may have paid for their therapy. Three patients had a PA approved but no subsequent paid claims for the therapy.

Recommendations:

- Designate products as either preferred or voluntary non-preferred based on evaluation of costs in executive session.
- Recommend removal of PA requirement for all OUD products except if dose limit of 24 mg buprenorphine per day is exceeded for transmucosal products (**Appendix 1**).
- Continue to monitor use of substance use disorder products to assess potential changes in medically appropriate use.

References:

1. House Bill 2257 (enrolled). 80th Oregon Legislative Assembly - 2019 Regular session. Available at https://olis.leg.state.or.us/liz/2019R1/Downloads/MeasureDocument/HB2257. Accessed 9/17/19.
2. Clinical Practice Guideline for Substance Use Disorders (2015). U.S. Department of Veterans Affairs/Department of Defense. http://www.healthquality.va.gov/guidelines/MH/sud/VADoDSUDCPGRevised22216.pdf. Accessed September 19, 2019.
3. Bruneau J, Ahamad K, Goyer ME, et al. Management of opioid use disorders: a national clinical practice guideline. *Canadian Medical Association journal.* 2018;190(9):E247-e257.
4. Canadian Agency for Drugs and Technologies in Health. Buprenorphine formulations for the treatment of opioid use disorders: a review of comparative clinical effectiveness, cost-effectiveness and guidelines. Ottawa: 2017 Jul. (CADTH rapid response report: summary with critical appraisal). https://www.cadth.ca/sites/default/files/pdf/htis/2017/RC0908%20Buprenorphine%20Formulations%20Final.pdf.

Appendix 1. Proposed Prior Authorization Criteria

Buprenorphine and Buprenorphine/Naloxone

Goals:

- Prevent use of high-dose oral buprenorphine products for off-label indications.
  ~~Encourage use of buprenorphine products on the Preferred Drug List.~~
- ~~Restrict use of buprenorphine products under this PA to management of opioid use disorder.~~
- ~~Restrict use of oral transmucosal buprenorphine monotherapy products (without naloxone) to pregnant patients or females actively trying to conceive.~~

Length of Authorization:

- Up to 6 months

Requires PA:

- ~~Buprenorphine sublingual tablets~~
- ~~Suboxone® and generics (~~Transmucosal buprenorphine~~/naloxone) film and sublingual tablets~~ products that exceed an average daily dose of 24 mg per day ~~of buprenorphine~~
- ~~Bunavail® (buprenorphine/naloxone buccal film)~~
- ~~Zubsolv® (buprenorphine/naloxone sublingual tablets)~~
- ~~Probuphine® (buprenorphine subdermal implants)~~
- ~~Sublocade™ (buprenorphine extended-release subcutaneous injection)~~

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. Is the diagnosis funded by the OHP?	**Yes:** Go to #2	**No:** Pass to RPh. Deny; not funded by OHP
~~Is the request for renewal of therapy previously approved by the FFS system?~~	~~**Yes:** Go to **Renewal Criteria**~~	~~**No:** Go to #3~~

Approval Criteria		
2. Is the prescription for opioid use disorder (opioid dependence or addiction)?	**Yes:** Go to #34	**No:** Pass to RPh. Deny; medical appropriateness
3. Is the prescription for a transmucosal formulation of buprenorphine (film, tablet) with an average daily dose of more than 24 mg (e.g., >24 mg/day or >48 mg every other day)?	**Yes:** Pass to RPh. Deny; medical appropriateness	**No:** Go to #4
~~Is the patient part of a comprehensive treatment program for substance abuse that includes psychosocial support system (e.g. individual and group counseling, intensive outpatient treatment, recovery support services, or 12-step fellowship)?~~	~~**Yes:** Go to #5~~	~~**No:** Pass to RPh. Deny; medical appropriateness.~~ ~~Buprenorphine therapy must be part of a comprehensive treatment program that includes psychosocial support.~~
~~Is the prescriber enrolled in the Oregon Prescription Drug Monitoring Program (www.orpdmp.com), evaluated the PDMP at least once in the past 6 months, and verified that the patient is not currently t prescribed any opioid analgesics from other prescribers?~~	~~**Yes:** Go to #6~~	~~**No:** Pass to RPh. Deny; medical appropriateness~~
~~3.~~4. Is the requested medication a preferred agent?	**Yes:** ~~Go to #8~~ Approve for anticipated length of treatment or 6 months, whichever is less. Note: Notify prescriber concomitant naloxone is recommended if not present in claims history.	**No:** Go to #5~~7~~

Approval Criteria		
~~4.~~5. Will the prescriber switch to a preferred product? Note: Preferred products are reviewed for comparative safety and efficacy by the Oregon Pharmacy and Therapeutics Committee.	**Yes:** Inform prescriber of covered alternatives in class.	**No:** ~~Go to #8~~ Approve for anticipated length of treatment or 6 months, whichever is less. Note: Notify prescriber concomitant naloxone is recommended if not present in claims history.
~~Is the request for the buprenorphine implant system (Probuphine)?~~	~~**Yes:** Go to #9~~	~~**No:** Go to #10~~
~~5. Has the patient been *clinically stable* on 8 mg daily or less of Suboxone or Subutex (or equivalent, see Table 1) for at least 6 months?~~ ~~Note: see Table 1 for definition of clinical stability and for equivalent dosing of other buprenorphine products.~~	~~**Yes:** If all criteria in Table 1 met, approve 4 implants for 6 months.~~ ~~Note: Notify prescriber concomitant naloxone is recommended if not present in claims history.~~	~~**No:** Pass to RPh. Deny; medical appropriateness~~
~~Is the request for extended-release subcutaneous buprenorphine injection (Sublocade™)?~~	~~**Yes:** Go to #11~~	~~**No:** Go to # 13~~

Approval Criteria		
~~Is the provider registered through the Sublocade™ REMS program?~~ ~~Note: Sublocade carries a boxed warning that stipulates healthcare settings and pharmacies that order and dispense Sublocade™ must be certified in the Sublocade™ REMS program and comply with the REMS requirements due to serious harm or death if this product is administered intravenously. Prescriber offices that only order Sublocade from a certified pharmacy for a specific patient are exempt from certification. Further information is available at www.SublocadeREMS.com or call 1-866-258-3905.~~	~~**Yes:** Go to #12~~	~~**No:** Pass to RPh. Deny; medical appropriateness.~~
~~6. Has the patient been clinically stable on a transmucosal buprenorphine-containing product at a dose of 8 to 24 buprenorphine per day (or equivalent-see note below) for a minimum of 7 days?~~ ~~Note: One Suboxone® (buprenorphine and naloxone) 8 mg/2 mg sublingual tablet provides equivalent buprenorphine exposure to one Subutex® (buprenorphine HCl) 8 mg sublingual tablet or one Bunavail® (buprenorphine and naloxone) 4.2mg/0.7 mg buccal film or one Zubsolv® (buprenorphine and naloxone) 5.7 mg/1.4 mg sublingual tablet~~ ~~Note: Notify prescriber concomitant naloxone is recommended if not present in claims history.~~	~~**Yes:** Approve 300mg once a month for 2 months followed by 100mg once a month for 6 months total~~ ~~Increasing the maintenance dose to 300mg once a month may be considered for patients who tolerate the 100mg dose but do not demonstrate a satisfactory clinical response as evidenced by self-reported illicit opioid use or urine drug screens positive for illicit opioid use.~~	~~**No:** Pass to RPh. Deny; medical appropriateness.~~
~~Is the prescription for a transmucosal formulation of buprenorphine (film, tablet) with an average daily dose of more than 24 mg (e.g., >24 mg/day or >48 mg every other day)?~~	~~**Yes:** Pass to RPh. Deny; medical appropriateness~~	~~**No:** Go to #14~~

Approval Criteria		
Is the prescribed product a buprenorphine monotherapy product (i.e., without naloxone)	**Yes:** Go to #15	**No:** Go to #17
Is the patient pregnant or a female actively trying to conceive?	**Yes:** Go to #17	**No:** Go to #16
Does the patient have a contraindication or intolerance to buprenorphine/naloxone combination products that prevents successful management of opioid use disorder?	**Yes:** Go to #17	**No:** Pass to RPh. Deny; medical appropriateness
What is the expected length of treatment?	Document length of therapy: _____ Approve for anticipated length of treatment or 6 months, whichever is shorter. Note: Notify prescriber concomitant naloxone is recommended if not present in claims history.	

Renewal Criteria		
1. Has the patient been assessed for the effectiveness of the treatment plan and overall progress that warrants continued treatment with buprenorphine?	**Yes:** Go to # 2.	**No:** Pass to RPh. Deny; medical appropriateness
2. Is the prescriber enrolled in the Oregon Prescription Drug Monitoring Program (www.orpdmp.com), and has the prescriber verified evaluated the PDMP at least once in the past 6 months, and verified that the patient is not currently has not been prescribed any opioid analgesics from other prescribers?	**Yes:** Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
3. Does the patient have a contraindication or intolerance to buprenorphine/naloxone combination products that prevents successful management of opioid use disorder?	**Yes:** Go to # 4	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria	
4. What is the expected length of treatment?	Document length of therapy: _____ Approve for anticipated length of treatment or 6 months, whichever is shorter. Note: Notify prescriber concomitant naloxone is recommended if not present in claims history.

Table 1. Criteria for Approved Use of Probuphine (buprenorphine implant).[1]

PROBUPHINE implants are only for use in patients who meet ALL of the following criteria: • Patients should not be tapered to a lower dose for the sole purpose of transitioning to PROBUPHINE • Stable transmucosal buprenorphine dose (of 8 mg per day or less of a sublingual Subutex or Suboxone sublingual tablet or its transmucosal buprenorphine product equivalent) for 3 months or longer without any need for supplemental dosing or adjustments: ○ Examples of acceptable daily doses of transmucosal buprenorphine include: ▪ Subutex (buprenorphine) sublingual tablet (generic equivalent) 8 mg or less ▪ Suboxone (buprenorphine and naloxone) sublingual tablet (generic equivalent) 8 mg/2 mg or less ▪ Bunavail (buprenorphine and naloxone) buccal film 4.2 mg/0.7 mg or less ▪ Zubsolv (buprenorphine and naloxone) sublingual tablets 5.7 mg/1.4 mg or less
Consider the following factors in determining clinical stability and suitability for PROBUPHINE treatment: • no reported illicit opioid use • low to no desire/need to use illicit opioids • no reports of significant withdrawal symptoms • stable living environment • participation in a structured activity/job that contributes to the community • consistent participation in recommended cognitive behavioral therapy/peer support program • stability of living environment • participation in a structured activity/job
Reference: PROBUPHINE (buprenorphine implant for subdermal administration) [Prescribing Information]. Princeton, MJ: Braeburn Pharmaceuticals, Inc., May 2016.

P&T/DUR Review: *1/19 (DM); 1/17; 9/16; 1/15; 9/09; 5/09*
Implementation: *3/1/2019; 4/1/2017; 9/1/13; 1/1/10*

Lofexidine

Goal(s):

- Encourage use of substance use disorder medications on the Preferred Drug List.

- Restrict use of lofexidine under this PA to ensure medically appropriate use of lofexidine based on FDA-approved indications.

Length of Authorization:

- Up to 14 days

Requires PA:

- Lofexidine 0.18mg tablets

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
• What diagnosis is being treated?	Record ICD10 code.	
• Is this an FDA approved indication? (Mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults)	**Yes**: Go to #3	**No:** Pass to RPh. Deny; medical appropriateness
• Will the prescriber consider a change to a preferred product? Message: • Preferred products do not require a PA. Preferred products are evidence-based reviewed for comparative effectiveness and safety by the Oregon Pharmacy & Therapeutics Committee.	**Yes:** Inform prescriber of covered alternatives in class.	**No:** Approve for up to 14 days of total therapy. Note: FDA approved indication is for up to 14 days of therapy AND Notify prescriber concomitant naloxone is recommended if not present in claims history.